

Adapting Pharmaceutical Pricing and Reimbursement Strategies for Achieving Universal Health Coverage in Nepal: Lessons from Selected Low- and Lower-Middle-Income Countries

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Universal health coverage is increasingly being embraced by low- and high-income countries alike, and pharmaceuticals are an integral part of it. With Nepal adopting national health insurance policy and willing to implement the same, guidance regarding pharmaceutical pricing, coverage and reimbursement becomes the order of the day. This study reviews pricing and reimbursement policies and techniques in low- and lower-middle-income countries which are implementing or intend to implement universal health coverage schemes, and provides recommendations on policies and techniques applicable and most pertinent to Nepal. For this, relevant literature on 11 countries was searched. The countries studied here are at different stages of universal health coverage, and they are aligning their pharmaceutical pricing and reimbursement policies and techniques with their universal health coverage policy. Considerable variation exists among these countries in regard to pricing, ranging from ceiling pricing (based on cost-plus, external referencing or market-based technique) to free pricing. All these countries have framed their essential medicines list; few or all of the medicines in the list are provided free of charge to targeted groups. Different universal health coverage schemes are at work in these countries, financing strategy for which span tax-based, premium-based and payroll deductions. Reimbursement decisions are intricately linked with pricing, with majority of the countries putting into effect a fixed reimbursable amount strategy for reimbursed products. In regard to Nepal, as it is beginning its universal health coverage journey, the ideal approach would be a ceiling price for essential medicines (applicable to both in-insurance and out-insurance) and reference or index pricing for reimbursed products.

Key words: Universal health coverage, pharmaceutical pricing, reimbursement, low- and lower-middle-income countries

Touted as a global health transition, third of its kind, Universal Health Coverage (UHC) has entered the health lexicon of low, middle and high-income countries alike^[1]. Countries are formulating and implementing their health policies with an eye to UHC. UHC was founded with two core objectives, to provide accessibility to health care services, and to provide financial risk protection for utilization of those services^[2]. It encompasses three elements namely health services, population, and proportion of cost^[3]. It necessitates a health services package, which is made available to the populace with no or minimal charge (in the form of co-payment, co-insurance or deductibles) at the time of service use^[3]. Among different health services covered, or considered to be covered, by

the health benefits package, pharmaceuticals pose a peculiar challenge.

Coverage of pharmaceuticals entails decisions regarding their pricing and reimbursement. Total pharmaceutical expenditure (TPE) is on the rise globally, accounting for an average 1.5% of global gross domestic product (GDP) in 2006^[4]. TPE has a share of 24.9%, on average, of total health expenditure (THE), with it ranging from 19.7% in high-income

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countries to 30.4% in low-income ones^[4]. Increase in TPE has outpaced both increase in THE and growth in GDP^[4,5]; as a result, pharmaceutical prices, pricing strategies and reimbursement schemes are getting all the more significant. Pricing and reimbursement has to strike a balance between encouraging innovation and providing wider access, resulting in a trade-off between the two^[6]. Further, unlike other health services, supply and availability of drugs are contingent on factors such as cross-border trade, making the pricing and reimbursement decision a tricky business.

A low-income country wedged between India and China, Nepal has gained tremendous achievements in health, with achieving of Millennium Development Goals (MDG) and targets of maternal mortality and under-five mortality and significant improvements in others^[7]. Further, health services at health posts and primary health care centers are available free of charge; however, out-of-pocket expenditure has significant share in cost of services, particularly in-patient and emergency ones, at secondary and tertiary hospitals^[8]. In the wake of health policy changes world-wide to accommodate UHC, Nepal formulated National Health Insurance Policy in 2013^[9]. This policy envisages a National Health Insurance Programme and anticipates a separate act for the same. Three districts *viz.* Kailali, Baglung and Illam have been selected for the first phase of the Social Health Security Program^[10]. Although these are early days for UHC in Nepal, Social Health Security Development Committee has been formed with the responsibility of registering health care providers and designing a health care package, pharmaceuticals included.

Nepal's pharmaceutical market is constituted by locally manufactured products (29%) and imported ones from India (54%) and multinational companies (MNCs) (17%)^[11]. Modern medicines, herbal preparations and veterinary products taken together, domestic manufacturers share 42% of market by value produced^[12]. The state has formed the National Essential Medicines List^[13], maximum of 70 of which are provided free of charge from health posts, primary health care centers and district hospitals. It constitutes only a small share of total drugs consumed and the remaining large share is priced. Also, the same 70 drugs are priced in the private sector, which accounts for 77% of TPE^[14]. According to Nepal National Health Accounts 2006/2007-2008/2009, medical goods sold in retail outlets account for around 28% of THE and around 48% of total out-of-pocket (OOP) health

expenditure^[14]. With the country planning to cover medicines, newer problems need to be tackled. Who shall determine the price? Should the pricing be left to market or should the government intervene? What type of reimbursement strategy needs to be adopted? What should be the extent of reimbursement? These are some of the questions that demand answers for effective and efficient coverage of medicines. This study reviews the available literature on pharmaceutical pricing and reimbursement policies adopted and techniques employed in different low and lower-middle-income countries. Also, it appraises their applicability and viability in the context of Nepal, and provides recommendations on future paths of Nepal *vis-a-vis* pharmaceutical pricing and reimbursement.

One thing to note here is that the "lessons" should not make us think that these countries have put to practice superior pricing and reimbursement policies; it could equally mean that there are shortcomings in these countries and Nepal would do well to redress them. It is likely that Nepal has better provisions than some of these countries. Also, these policies undergo changes in the face of changing economic condition and political leadership, and as these countries are at different stages of UHC, revisions are more than likely. The purpose of this study, thus, is to juxtapose the current pricing and reimbursement practice in Nepal against those in similar countries and to glean information on paths that need to be avoided and choices that can be availed of.

MATERIALS AND METHODS

First, I searched for literature on UHC for low and lower-middle-income countries. I selected countries which are at different stages of UHC, including the ones which have committed on paper to pursue it. For these countries, I looked for literature on pharmaceutical pricing and reimbursement policies. I found 11 such countries, which were selected for literature review. These were: Bangladesh, India, Sri Lanka, Vietnam, Philippines, Indonesia, Rwanda, Moldova, Ghana, Ethiopia and Nigeria. These countries met the following inclusion criteria: low or lower-middle income economy; have adopted UHC policies or are beginning to pursue UHC or are at different stages of UHC and have high-quality literature on pharmaceutical pricing and reimbursement.

I searched MEDLINE database (via PubMed), WHO library, Cochrane Reviews Database, World Bank eLibrary and OECD iLibrary. Other published and

unpublished papers were searched for and accessed via Google Scholar search engine.

RESULTS AND DISCUSSION

Pharmaceutical pricing and reimbursement practice is embedded in health care decisions and adoption of UHC policies in health care warrants changes in it. After adopting health insurance scheme in 2008, Vietnam introduced price stabilization provision wherein the government would fix the price of reimbursed products^[15]. Ghana had a similar course of events, with the framing of National Health Insurance Authority (NHIA) medicine list and a specified amount for each for reimbursement after instituting National Health Insurance scheme^[16]. Even in the absence of UHC practices on the ground, pharmaceutical pricing practice can undergo changes if not an overhaul, as is evidenced in India^[17]. High Level Expert Group has recommended a tax-based financing to achieve UHC in India, with proactive government intervention for price regulation on the ground of essentiality^[17]. Although not much has been done in regard to UHC, National Pharmaceuticals Pricing Policy was formulated in 2012 followed by revision of Drug Price Control Order in 2013^[18]. Bangladesh, on the other hand, has framed Health Care Financing Strategy 2012-2032 and is on the way to launch pilot phase, but has not given adequate attention to pharmaceutical pricing as pricing mechanism has not been updated^[19].

Pharmaceutical pricing is not seen in isolation, and is considered in conjunction with their quality and supply. These countries require licensing of manufacturers and importers and prior marketing authorization (registration) of the products. Pharmaceuticals from local manufacturers make up a significant proportion of total pharmaceuticals consumed in countries such as India^[18], Bangladesh^[20], Philippines^[21], Vietnam^[15] and Indonesia^[22]. Of note is the feature that all these countries are specialized in production of generic products (including branded ones of off-patent products). There is, further, a trend of encouraging MNCs to open local production plants, thereby decreasing reliance on import. On the other end of the spectrum are countries such as Rwanda^[23], Moldova^[24], Ethiopia^[25], Ghana^[26] and Nigeria^[27], which are heavily, even exclusively (Rwanda), dependent on import and foreign donations. Problematic in all these countries is the price of patented drugs, which render those products unaffordable. While countries with scores of reputable and high-quality generic manufacturers rely

on stringent requirement for patent registration and compulsory licensing, which are in line with Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, others are sustained by import from these countries, foreign aids and charity. Alternatively, tiered pricing has been practiced in a few countries, but empirical evidences for its success are mixed^[28,29].

The concept of essential medicines is more or less embraced by these countries, although there is variation in the provision surrounding their pricing and availability. Essential medicines in general are more available than non-essential ones, reflecting as it does the significance of the concept^[30]. Countries with a solid public health sector, such as Sri Lanka, have strong procurement system, better availability and lower and affordable price of essential medicines; in fact, medicines are available free of charge from retail pharmacies of State Pharmaceuticals Corporation and at affordably low price from private outlets^[31]. In most of these countries, governments have a role to play in pricing and availability of essential medicines. India fixes ceiling price of drugs on the grounds of essentiality^[18]. Bangladesh has the provision of a ceiling price, based on cost-plus pricing technique, for essential medicines, while other medicines are left to market forces for their price determination^[20]. India^[18] and Bangladesh^[32] provide them from public health facilities free of charge or for a subsidized price. Indonesia also provides them free of charge from public sector pharmacies^[22]. Philippines has Essential Drug Price Monitoring System (EDPMS) for nationwide monitoring of essential medicines from drugstores on a monthly basis^[33]. An Essential Drug Price Monitoring Oversight Committee in Philippines provides recommendations to Secretary of Health for price ceilings of essential medicines^[33]. Moldova^[24], Ethiopia^[25], Ghana^[26] and Nigeria^[27] provide free of charge medicines for tuberculosis, HIV/AIDS and malaria and vaccines under Expanded Program on Immunization for children. Health Insurance schemes in Moldova^[24] and Ghana^[26] cover all medicines listed in national Essential Medicines List (EML) for both in-patient and out-patients. While Community-Based Health Insurance (CBHI) in Rwanda provides coverage to limited number of essential medicines, RAMA and MMI, two social health insurance schemes for civil servants and servicemen, cover all essential medicines^[34].

There is considerable variation among these countries in pricing policies for pharmaceuticals. Ethiopia^[25],

Ghana^[26] and Nigeria^[27] practice free pricing, wherein companies have the authority to set price for their products. Ethiopia has a three-tiered retail outlet system for medicines, which is heavily privately owned^[35]; further, inverse relation has been observed between price and availability^[36]. Non-uniformity in prices exists across different geographical regions in Ghana, which has to rely on private sector even for procurement in public sector^[37]. Cost recovery method is practiced there for pricing in public sector^[38]. Exceedingly high price as compared to international price, low availability across all sectors and affordability issue encapsulate medicines scenario in Nigeria^[39]. Moldova has the provision for price regulation in the form of registration price system i.e. price is fixed at the time of product registration: prices are fixed by external price referencing across 15 countries, in which the average of lowest prices in three countries is considered^[40]. Sri Lanka used to fix ceiling price prior to 2002; nowadays, companies are free to set their prices, although maximum retail price needs to be displayed on products^[31]. For non-essential products, India^[18] and Bangladesh^[20] also practice free pricing with the requirement of maximum retail price on products. Indonesia also requires that maximum retail price be displayed; she practices ceiling pricing for essential medicines, wherein maximum retail margin of 50% is set^[41]. Vietnam has the requirement of declaring wholesale price and retail mark-up to Ministry of Health for reimbursable products^[15]. This is followed by price stabilization by State, accomplished by employing external price referencing and cost-plus pricing for referencing, five countries *viz.* Thailand, Malaysia, Indonesia, Philippines and Cambodia have been proposed, although this has yet to be put into practice^[15]. Philippines has in place drugs price monitoring, with monthly data collection of drug prices and annual comparison with international price^[33]. Further, prices for 185 drugs have been published, termed as Drug Price Reference Index (DPRI), which help maintain price transparency and work as ceiling prices for reimbursement^[33]. Among the Asian countries studied here, Bangladesh generally has lowest price, followed by Sri Lanka and India^[20]. For public pharmaceutical sector, all these countries have implemented procurement via tendering on a competitive basis, a form of indirect price regulation.

Health insurance works as an indirect form of price control (*de facto* control), with techniques such as selected listing of drugs in the formulary and fixing

of maximum reimbursable amount in practice. Vietnam practices price stabilization for the Social Health Insurance Scheme, in which the maximum reimbursable amount is determined by the State^[15,42]. Indonesia has recently introduced compulsory national health insurance program by combining fragmented health insurance schemes such as Askes, Jamsostek and Jamkesmas which intends to provide coverage to pharmaceuticals listed in national formulary formed on the basis of advice from scientific communities (in line with Askes scheme)^[36]. In Askes scheme, a fixed amount is reimbursed, and an annual reimbursement list is published^[36]. Philippines publishes Philippine National Drug Formulary (PNDF), the drugs listed on which are reimbursed^[33] and has also adopted pharmacoeconomic and cost-effectiveness approach to take decision on reimbursement of non-PNDF drugs^[33]. Further, setting a maximum reimbursable amount is practiced for in-patient medicines; out-patient ones have to be borne by the person out of pocket^[21,33]. Tax-based health coverage is at work in Sri Lanka, wherein medicines are distributed freely from retail pharmacies owned by State Pharmaceuticals Corporation^[31]. India has also proposed tax-based financing for UHC^[17], although its implementation is lacking. Bangladesh has framed health financing strategy, which envisages a mixed model (combination of tax-based financing, contributory scheme in the form of premium and social health insurance scheme) for achieving UHC^[19]. Both Bangladesh and India have yet to come up with their reimbursement strategies. Moldova has instituted mandatory health insurance scheme with contributions from payroll taxes and flat payment^[43]. Moldova has a small list of essential medicines which is reimbursed, the extent of reimbursement being dependent on level of care and geographical location^[44]. Ghana has achieved significant gains in health coverage with her national health insurance scheme^[45]. Medicines listed in NHIA medicine list are reimbursed, which is more comprehensive than essential medicines list; the reimbursed amount is fixed, determined by employing median pricing method^[16]. Nigeria, on the other hand, has yet to achieve significant coverage through its insurance scheme^[46]. Countries such as Rwanda^[34] and Ethiopia^[35] have banked on CBHI for health coverage. Rwanda through Mutuelles (CBHI), RAMA and MMI has attained near universal coverage, with pharmaceuticals covered based on essential medicines list and the extent of coverage depending on the type of insurance scheme^[34]. One common feature among all these countries is that medicines for certain targeted

groups are fully or partially subsidized, irrespective of the health insurance scheme in place.

Pricing policies and UHC scheme-both proposed and practice-in these countries are summarized in Table 1.

There is a dearth of literature on pharmaceutical pricing and reimbursement in low and lower-middle-income countries (LLMIC), in general. Significantly, research on impact evaluation of pricing and reimbursement policies is severely limited and more research is warranted in this regard. Studies on such policies and their effect on price, availability and affordability of medicines abound for high-income countries; however, extrapolation of the results to LLMIC has been questioned^[47]. Nevertheless, organizations such as World Health Organization (WHO) and Health Action International (HAI) and researchers at academic institutions are striving to generate evidences in these countries.

It has been observed in developing countries that medicines procurement price in public sector is marginally higher than international reference price, while prices in private sector are exceptionally high (9-25 times international reference price for lowest-priced generics)^[48]. Although pricing policies in the countries studied here vary from free pricing to ceiling pricing, common features such as high prices (particularly in the private sector) and restricted availability (particularly in the public sector) characterize majority of them. Both high, unaffordable prices and limited availability ultimately constrain access, accentuating the fact that acting on only one of them would not suffice. This lack of access to medicines is one of the major bottlenecks for UHC as well, for both financial risk protection (compromised by high prices) and access to services (compromised by both high, unaffordable price and limited availability) are compromised. Also, it shows that price control-either through competition or in the form of government regulation and procurement system in place have not been effective. Those generic prices in these countries, which are predominantly generic markets, are multiple times international price seem counter-intuitive. Likely explanations, particularly for high prices in private sector, could be: these are not competitive markets and competition in the economic sense (the one that drives prices low) is absent and purchasers do not buy into the generic product concept (either due to lack of information on generics or uncertainty over their quality and efficacy) and prefer products from well-established manufacturers. Studies

on private pharmaceutical markets of Philippines and Bangladesh have shown that they have a preference for branded generics^[49]. Likewise is the scenario in India, Indonesia and Vietnam. A study on prices of reproductive health medicines in Nepal revealed, although prices across all sectors were low than in countries such as Philippines and Kenya, price variation between branded and non-branded generics remained^[50]. This indicates that manufacturers, in countries studied here including Nepal, compete on brand value than on price, unlike in high-income countries, leading to high prices in private sector. In the public sector, inefficiency in procurement system has been a major shortcoming. A comprehensive study has observed that entrance of a new generic manufacturer in a thriving generic market would result in only a nominal decrease in price, while competitive tendering and efficient procurement would translate to marked decrease^[51]. Sri Lanka with a sound procurement system has been able to purchase medicines at low prices. Better procurement strategies are therefore warranted for low and affordable price in public sector. Further, as medicines are distributed free of charge from public pharmacies in Sri Lanka, prices are low in private outlets because of the competition with freely available ones of public sector. A study has pointed out shortcomings in procurement of medicines in the public sector of Nepal and has highlighted rooms for improvement^[52]. All this calls for proactive public sector involvement in procurement, for this has direct bearing on prices in both public as well as private sector.

Some form of government intervention is justified with reference to pharmaceutical pricing and reimbursement, particularly in a low-income country such as Nepal. Factors such as asymmetry of information, minimal involvement of consumers in choosing the products, and direct relation of the products with morbidity and mortality do not allow the pharmaceutical market to be solely left to market forces without detrimental effects on health^[51]. There is little doubt about whether the quality aspect of pharmaceuticals should be regulated; with the quality factor having the potential of hazardous impact on health, it is mandatory across countries for manufacturers and products to meet certain quality requirements. One thing generally overlooked is the spill-over effect of this well-regulation of quality on prices. It has been argued that enforcement of competition laws and implementation of regulatory guidelines for quality and safety could lead to better price competition and low prices^[53]. Apropos of direct

TABLE 1: UHC SCHEME AND PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES IN SELECTED 11 LOW- AND LOWER-MIDDLE-INCOME COUNTRIES

Country	UHC scheme	Pricing policy (proposed or in practice)
India	Tax-financed health coverage is proposed.	<ul style="list-style-type: none"> • Ceiling pricing for essential medicines. Earlier determined by cost-plus technique; replaced by market-based one. • Price for non-essential ones determined by the market. • Requirement for displaying of maximum retail price for all medicines.
Bangladesh	Health financing strategy for achieving UHC is proposed, which intends to generate fund from a combination of general taxes, flat insurance premiums and payroll deductions.	<ul style="list-style-type: none"> • Ceiling pricing for essential medicines by cost-plus technique. • Free pricing for non-essential ones. • Maximum retail price required.
Sri Lanka	Tax-based coverage is in practice.	<ul style="list-style-type: none"> • Medicines available free of charge from State Pharmaceuticals Corporation-owned retail pharmacies. Procured by competitive international tendering. • Free pricing for medicines in private outlets. Prices affordable owing to competition with freely available medicines in public outlets.
Vietnam	Social health insurance scheme is in practice.	<ul style="list-style-type: none"> • Free pricing by companies with price stabilization by the state. • Wholesale price and retail mark-up declared to Ministry of Health. Published price not higher than declared one. • Price stabilization accomplished by External Price Referencing (EPR). Comparator countries for EPR and cost-plus pricing proposed, but yet to be implemented.
Indonesia	National health insurance program has been introduced, by combining Askes, Jamsostek and Jamkesmas schemes.	<ul style="list-style-type: none"> • Ceiling price for essential medicines fixed, with 50% of maximum retail margin. • Maximum retail price required.
Philippines	National health insurance program has been implemented.	<ul style="list-style-type: none"> • Essential drug price monitoring system in place for nationwide monitoring of prices from drugstores on a monthly basis and for fixing of ceiling prices for them. • Publishing of drug prices along with international price on an annual basis.
Moldova	National health insurance scheme is in practice.	<ul style="list-style-type: none"> • Registration price system in place. • Price fixed by EPR, using 15 comparator countries, in which the average of lowest prices in three countries considered.
Ghana	National health insurance scheme is in practice.	<ul style="list-style-type: none"> • Free pricing by manufacturers (both local and foreign). Limits on wholesale and retail mark-up on ex-manufacturer's price. • Fixed reimbursable amount for drugs in NHIA medicine list, based on median pricing technique.
Nigeria	National health insurance scheme is in practice. Coverage is very low, though.	<ul style="list-style-type: none"> • Free pricing by manufacturers. • No regulation of mark-ups.
Ethiopia	Community-Based Health Insurance is in practice. Social Health Insurance scheme has been proposed.	<ul style="list-style-type: none"> • Free pricing by manufacturers. High mark-ups due to lack of regulation. • International tendering by public sector functioning as an indirect form of price control.
Rwanda	Mutuelles scheme (CBHI), RAMA (SHI) and MMI (SHI) are in practice.	<ul style="list-style-type: none"> • Free pricing by manufacturers. • Minimal presence of local manufacturers; medicines exclusively imported.

price regulation, however, theories and evidences are divided. This fragmentation is in part due to different provisions for different categories of medicines (patented versus generics, prescription versus over-

the-counter). In high-income countries, some form of regulation is in place for patented and prescription medicines. One thing to notice here is the fact that majority of these high-income countries have universal

coverage for health services, and price regulation in the form of either maximum allowable price or maximum reimbursable amount would apply uniformly to all. But LLMICs are at different stages of UHC, and regulating just the reimbursable amount could lead to price disparity between covered and non-covered people (higher price for non-covered people). In addition, as civil servants and formal sector employees are easily covered, this price disparity could translate into inequity in affordability and utilization. Also, unlike high-income countries, there is competition on brand value for generics, as mentioned earlier. It is advisable, then, to LLMICs including Nepal to regulate prices irrespective of reimbursement scheme and to control price of generics as well. This should be followed by fixing of reimbursable amount for covered people. Ceiling pricing, irrespective of reimbursement scheme, is already at work in countries such as Bangladesh, India and Indonesia. Although Nepal practices free pricing with regulated mark-ups and the requirement of displaying of maximum retail price, it has nevertheless experimented with ceiling pricing for paracetamol preparations, IV fluids and albendazole tablet and suspension^[54,55]. This practice is being expanded to include all medicines in the Essential Medicines List.

Effectiveness and applicability of pricing techniques such as cost-plus pricing, reference pricing, index pricing are other areas of concern. Prices in Nepal are at present fixed by manufacturers based on the prices of existing similar products^[54] and there is need for exploiting better techniques for setting the prices. WHO has issued guidelines on how to utilize pricing techniques in low and middle-income settings^[56]; however, they do not consider pricing policies and techniques in the light of UHC policies. Although study has shown that reference and index pricing lead to lower expenditure, this is realized easily under an insurance scheme^[57]. As LLMICs are at different stages of UHC, pharmaceutical pricing guidelines catering to their UHC progress are the need of the hour.

With countries such as Rwanda and Moldova doing significant works in regard to UHC, it is clear that UHC is not a prerogative of high-income countries and not a provision only in socialist countries. Sustained health financing and long-term political commitments are paramount for a country like Nepal to achieve UHC. As providing access to medicines is an important objective of UHC, decisions regarding coverage of medicines (their pricing and reimbursement) are inevitable. Clear-cut pharmaceutical pricing and reimbursement

policies, proactive role of government in regulation and procurement, routine price monitoring and publishing of the same in conjunction with international price and pharmacoeconomic evaluations are requisites of a successful pricing and reimbursement scheme. Nepal should endeavor to put these into practice. Also, as Nepal is beginning its UHC journey, the ideal approach would be ceiling price for essential medicines (applicable to both in-insurance and out-insurance) and reference or index pricing for reimbursed products.

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